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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,591	02/06/2002	Duojia Pan	B01-019-2	1004

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,591	PAN ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) *19 and 22-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18, 20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/13/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pan *et al.*
Priority Date : 10/27/2000

DETAILED ACTION

Applicant's Election

The Election filed on 02/06/2004 in response to the Office Action of 01/22/2004 is acknowledged and has been entered. Claims 18-34 are currently pending. Claims 19, and 22 – 34 are withdrawn from consideration as being drawn to non-elected species. Claims 18, 20-21 are currently under consideration.

Applicant's election with traverse of Group I, claims 19-34 is acknowledged. The traversal is on the ground(s) that the species each specify a different small molecule metalloprotease inhibitor, wherein, the function of the inhibitor is the same in each dependent claim i.e., they merely substitute one functionally equivalent small molecule inhibitor for another. This is not found persuasive. Here, the species of Group I represent separate and distinct molecules such that one species could not be interchanged with the other.

Different searches and issues are involved in the examination of each species. For these reasons the species requirement is deemed to be proper and is therefore made FINAL.

Species/Election

Claim 20, wherein the metalloprotease inhibitor is IC-3 (N-{D, L-[2-(hydroxyaminocarbonyl)methyl]-4-methyl-pentanoyl}-L-alanine, 2-aminoethyl amide) is **FREE OF THE PRIOR ART**. Therefore, claim 21 was selected as the next species for examination.

Specification

An amendment to the specification filed on 02/06/2006 (page 2) was not entered for the following reason: It does not appear that information pertaining to a replacement paragraph was either scanned or requested (Please see attachment). Applicants are requested to re-file the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for inhibiting angiogenesis comprising the steps of; contacting a vertebrate animal predetermined to have a pathogenic angiogenesis with a metalloprotease inhibitor to specifically inhibit the activity of Kuz in the animal; and detecting a resultant inhibition of angiogenesis in the animal. The claims do not require that Kuz possess any particular biological activity, nor any particular conserved structure or other disclosed distinguishing feature. The specification teaches (page 4, line 2) that Kuz refers to an art-recognized family of natural proteins which have been extensively described, encompassing natural orthologs and variants also well know in the art. Thus, the claims are drawn to a genus of metalloproteases that is defined only by the name Kuz.

To provide adequate written description and evidence of possession of the claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure/function correlation, method of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a molecule referred to as Kuz. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Makaukar, 19USPQ2 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention.* The invention is, for the purpose of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1016 at 1601 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Claim 18, 20-21 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are not *enabled*, because one of ordinary skill in the art could not use the invention with any predictability because the claims do not specifically limit what is included or excluded by recitation of Kuz. Applicants argue (Page 4, line 2) that Kuz refers to an art-recognized family of natural protein which have been extensively described, encompassing natural orthologs and variants also well know in the art. For example, several forms of human KUZ have been described including WO98/37092 and WO97/31931; Mayer et al. (US Pat. No. 5, 922,546); and Rubin et al. (US Pat No. 5,935,792). However, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569,

179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Galardy *et al.* (Cancer Res. 1994, Vol. 54, No. 17, pages 4715-18).

Galarady et al. teach a method for inhibiting angiogenesis comprising contacting a vertebrate animal predetermined to have a pathogenic angiogenesis with a metalloprotease inhibitor wherein said inhibitor is GM6001 and detecting the resulting inhibition of angiogenesis in the animal. Specifically, Galarady et al teach "that GM6001, an inhibitor with specificity for the MMPs, significantly reduces the number and area of new vessels in rat corneas implanted with Hydron pellets containing an extract of the malignant tumor Walker 256 carcinosarcoma (pg. 4215. 2nd column, 1st paragraph)."

Although the reference does not specifically teach GM6001 specifically inhibiting the activity of "Kuz", the claimed functional property is an inherent property of GM6001. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, Ph. D
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER